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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,476	07/25/2003	Markus Pompejus	BGI-125CPCN	2236
959	7590	11/06/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			BRUSCA, JOHN S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/627,476	POMPEJUS ET AL.
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 August 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3,9-17,25,26 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) 25,26 and 28-35 is/are withdrawn from consideration.
- 5) Claim(s) 36-38 is/are allowed.
- 6) Claim(s) 3 and 9-17 is/are rejected.
- 7) Claim(s) 39 and 40 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 09/602787.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/4/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 25-35 are directed to a process of making or using a product. The product was elected in the response filed 12 February 2006. Pursuant to the procedures set forth in MPEP § 821.04(B), claims directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, will be rejoined and fully examined for patentability under 37 CFR 1.104. In response to the query of the applicants on this point in their response filed 14 August 2006, it is noted that if the instant product claims are found to be allowable, claims 25, 26, 28-35, drawn to methods of using the product, would be rejoined for examination on the merits.

### ***Claim Rejections - 35 USC 101 and 112***

2. The rejection of claims 3, 9-17, and 36-38 under 35 U.S.C. 101 because the claimed invention lacks patentable utility in the Office action mailed 13 April 2006 is withdrawn in view of the arguments presented in the applicant's response filed 14 August 2006.
3. The rejection of claims 3, 9-17, and 36-38 under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial utility or a well established utility such that one skilled in the art clearly would not know how to use the claimed invention in the Office action mailed 13 April 2006 is withdrawn in part for claims 36-40 limited to compositions comprising genes that encode a polypeptide with cysQ activity.
4. The rejection of claims 3 and 9-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the Office action mailed 13 April 2006 is

withdrawn in view of the arguments and amendment presented in the applicant's response filed 14 August 2006.

5. The rejection of claim 37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 13 April 2006 is withdrawn in view of the arguments and amendment presented in the applicant's response filed 14 August 2006.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising genes that encode a polypeptide with cysQ activity, does not reasonably provide enablement for fragments of SEQ ID NO:5 that do not encode a polypeptide with cysQ activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

- a) In order to practice the claimed invention one of skill in the art must use compositions comprising a fragment of SEQ ID NO:5 as small as 15 nucleotides. For the reasons discussed below, there would be an unpredictable amount of experimentation required to use the claimed compositions.
- b) The specification does not provide specific guidance to use compositions comprising fragments of SEQ ID NO:5 that do not encode a polypeptide with cysQ activity.
- c) The specification does not provide working examples of using compositions comprising fragments of SEQ ID NO:5 that do not encode a polypeptide with cysQ activity.
- d) The nature of the invention, molecular biology of *Corynebacterium glutamicum*, is complex.
- e) The prior art does not serve to supplement the guidance of the specification for using compositions comprising a fragment of SEQ ID NO:5 as small as 15 nucleotides because the prior art does not show SEQ ID NO:5.
- f) The skill of those in the art of molecular biology is high.
- g) The prior art does not predict how to use compositions comprising a fragment of SEQ ID NO:5 that does not encode a polypeptide with cysQ activity
- h) The claims are broad in that they are not limited to compositions comprising genes that encode a polypeptide with cysQ activity. The applicants have established that SEQ ID NO:5 encodes a polypeptide with cysQ activity in the specification, and have pointed to evidence for a well recognized utility for such compositions in their response filed 14 August 2006. However a utility for compositions comprising fragments of SEQ ID NO:5 that do not encode a polypeptide

with cysQ activity has not been noted in the specification, or the applicant's response filed 14 August 2006, and is not well recognized in the prior art.

The skilled practitioner would first turn to the specification to practice embodiments of the claimed subject matter that do not include a fragment of SEQ ID NO:5 that encodes a polypeptide with cysQ activity. However the specification lacks such guidance or working examples. The skilled practitioner would then turn to the prior art for such guidance, but the prior art does not show SEQ ID NO:5. Finally said practitioner would turn to trial and error experimentation to use embodiments of the claimed subject matter drawn to fragments of SEQ ID NO:5 that do not encode a polypeptide with cysQ activity. Such represents undue experimentation.

### ***Double Patenting***

The provisional rejection of claims 3, and 9-17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 8-17 of copending Application No. 11/055822 in the Office action mailed 13 April 2006 is withdrawn in view of amendments to the copending claims of Application No. 11/055822 filed 22 August 2006.

### ***Allowable Subject Matter***

8. Claims 36-38 are allowable.
9. Claims 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*John S. Brusca 26 October 2006*

John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb